STERILMED, INC.
Medical Device Reprocessing
Small Equipment & Instrument Repair

K110076 AUG 18 2011

January 10 2011
For Reprocessed 3D Diagnostic Ultrasound Catheters

I. SUMMARY AND CERTIFICATION

A. 510(k) Summary

Submitter: SterilMed, Inc.

Contact Person: Onya Dendinger
11400 73rd Avenue North
Maple Grove, MN 55369
Ph: 763-488-3410
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Date Prepared: January 10, 2011

Trade Name: Reprocessed 3D Diagnostic Ultrasound Catheter

Classification Name: Diagnostic Intravascular Catheter

Panel: 74

Classification Number: 21 CFR § 870.1200

Product Code: OWQ, Catheter, Intravascular Ultrasound, Reprocessed

Class: II

Predicate Devices:	The Reprocessed 3D Diagnostic Ultrasound Catheters are substantially equivalent to the Biosense Webster, Inc. SoundStar™ 3D Diagnostic Ultrasound Catheter (510(k) K070242) and the AcuNav™ Diagnostic Ultrasound Catheter (510(k) K033650).
Device Description:	SterilMed Reprocessed 3D Diagnostic Ultrasound Catheters are specially designed catheters that provide two-dimensional imaging using an ultrasound transducer and three-dimensional location information using a location sensor. The ultrasound transducer and location sensor are at the distal tip of the catheter and can be positioned for ultrasound imaging and 3D mapping by a steering mechanism that rotates the catheter tip and provides variable deflection. 3D Diagnostic Ultrasound Catheters incorporate a hand piece, a flexible shaft and a distal tip section containing an ultrasound transducer and a location sensor. The ultrasound transducer of this device has an acoustic array that is identical to the AcuNav™ 10F Diagnostic Ultrasound Catheter. The 3D Diagnostic Ultrasound Catheter's 3D location sensor provides location information to the CARTO® XP EP Navigation System (mapping system). The 3D Diagnostic Ultrasound Catheters is 10 French with a 90 cm insertion length. Note: Only the catheter is the subject of this submission; accessories and/or any other related equipment are not included in the scope of this submission.
Intended Use:	The Reprocessed 3D Diagnostic Ultrasound Catheters are indicated for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. The 3D Diagnostic Ultrasound Catheter provides location information when used with the CARTO® XP EP Navigation System Version 9 or greater.
Functional and Safety Testing:	Representative samples of Reprocessed 3D Diagnostic Ultrasound Catheters were tested to demonstrate appropriate functional characteristics. Process validation testing was performed to validate the cleaning and sterilization procedures as well as device packaging. In addition, the manufacturing process includes visual and validated functional testing of all products produced.
Summary of Non-clinical Tests Conducted:	Specific non-clinical tests performed included: cleaning validation, sterilization validation (ISO 11135, USP <71>), biocompatibility testing (ISO 10993-1), ethylene oxide residual testing (ISO 10993-7), biological testing, cleaning residuals, packaging validation (ASTM D4169, ASTM F88, ASTM F2096), and shelf life validation (ASTM 1980-99). In addition, functional performance (including both the ultrasound and 3D location sensor components) and mechanical reliability were validated using bench and laboratory testing. The testing which was performed include Hipot testing (IEC 60601-1:2005, Cause 8.8.3), defibrillation testing (IEC 60601-1:2005, Clause 8.5.5.1), and temperature heating (IEC 60601-2-27).

Conclusion:	The Reprocessed 3D Diagnostic Ultrasound Catheters are substantially equivalent to the Biosense Webster, Inc. SOUNDSTAR™ 3D Diagnostic Ultrasound Catheter and AcuNav™ Diagnostic Ultrasound Catheter. This conclusion is based upon the devices' similarities in functional design (principle of operation), materials, indications for use and methods of construction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SterilMed, Inc.
c/o Ms. Onya Dendinger
Regulatory Affairs Manager
11400 73rd Avenue North
Maple Grove, MN 55369

AUG 18 2011

Re: K110076
Trade/Device Name: Reprocessed 3D Ultrasound Catheter (See Enclosed List)
Regulatory Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: II (two)
Product Code: 74 OWQ
Dated: July 15, 2011
Received: July 18, 2011

Dear Ms. Dendigner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEVICE MODEL COVERED BY THIS SUBMISSION:

Manufacturer	Trade Name	Description
Biosense Webster, Inc.	SoundStar™ 3D Ultrasound Catheter	SNDSTR10 – 10 French, 90 cm length

Indications for Use

510(k) Number (if known): K110076

Device Name: Reprocessed 3D Diagnostic Ultrasound Catheters

Indications for Use:

The Reprocessed 3D Diagnostic Ultrasound Catheters are indicated for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. The 3D Diagnostic Ultrasound Catheter provides location information when used with the CARTO® XP EP Navigation System Version 9 or greater.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110076